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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,964	11/19/2001	Avi J. Ashkenazi	P1110C1	1355

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EXAMINER
KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
1646	11

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/992,964	Applicant(s) ASHKENAZI ET AL.	
	Examiner Claire M. Kaufman	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2001 and 25 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-21 and 30-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *105-110 and 112* is/are allowed.

6)☒ Claim(s) *15-21,30-104 and 111* is/are rejected.

7)☒ Claim(s) *32,42,44,46,60 and 75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,9,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

Applicants are advised that the ATCC has moved from Rockville, MD to Manassas, VA, effective March 23, 1998. The correct address is now:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

The specification should be amended to reflect the correct address for the ATCC (see for example p. 49, line 30, p. 59, line 6 and p. 76, lines 3-4).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 57-59, 61-73, 74 and 76-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 33, 49, 67, 81 and 97 require the isolated nucleic acid to comprise a polynucleotide sequence encoding a Fc polypeptide. No basis in the specification could be found for such a nucleic acid comprising an Fc encoding region wherein the nucleic acid does not encode an active antibody. While the specification discusses Fab antibody fragments, chimeric proteins, immunoadhesions and humanized antibodies that comprise Fc domains (*e.g.*, p. 16, 17 and 40-44), there is no discussion of a polypeptide specifically comprising both an Fc domain and a non-antibody domain as required by the claims.

Claim 57 recites polynucleotide sequences encoding a polypeptide comprising the amino acid sequence of residues m to 259 and/or 1 to x of SEQ ID NO:1, where m is an integer in the range of 1 to 53 and x an integer in the range of is 149 to 259. No basis in the specification could be found for such fragments or the concept of a polypeptide comprising such a range of amino acids.

Claim 74 recites a nucleic acid encoding a polypeptide comprising 30 contiguous amino acids from amino acids from amino acids 27-259 of SEQ ID NO:1. This claim has new matter for two reasons. First, no basis in the specification could be found for "a polypeptide comprising 30 contiguous amino acids". Second, no basis could be found for the fragment of amino acids 27-259 of SEQ ID NO:1, though there is basis for 30-259.

Claims 76 and 88 recite a means of calculating percentage sequence identity. While there is basis for calculating % identity (p. 13, lines 9-23), there is no basis for allowing "gaps of up to 10% of the total number of nucleotides...."

These claims were added by preliminary amendment and no basis in the specification as filed could be found as discussed above. The dependent claims listed in the preamble of the rejection require the limitation discussed above, and therefore, are also rejected as containing new matter. Applicants have not provided page and line number where basis in the specification can be found for these claims.

Claims 30, 31, 33-41, 43, 45, 47-58, 61, 63, 65-73, 76, 77, 79, 89, 92 and 93-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to an isolate nucleic acid that comprises a polynucleotide at least 90% or 95% identical to a second polynucleotide that encodes a polypeptide with a specified sequence. While the specification describes a nucleic acid which encodes a polypeptide with at least 80% identity to amino acids 1-259 of SEQ ID NO:1 or the Apo-2DcR polypepide encoded by the cDNA clone contained in ATCC Deposit No. 209087, wherein said polypeptide binds Apo-2 ligand, it does not describe nucleic acids comprising a polynucleotide sequence that is not

identical to another encoding polynucleotide sequence. Because of degeneracy of the genetic code, there are a myriad of polynucleotides which can encode one polypeptide sequence. To say, further, that the first polynucleotide, which can be a degenerate sequence, is not the same as or is up to 5-10% different than the second encoding polypeptide, is to add even more diversity to the polynucleotides encompassed by the claims. The specification teaches one encoding polypeptide for Apo-2DcR, SEQ ID NO:1. The specification does not teach such a diverse array of nucleic acids claimed, and it does not appear that Applicants were in possession of such a group of nucleic acids.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Therefore, only the nucleic acid encoding SEQ ID NO:1 or recited fragments thereof or the nucleic acid which encodes a polypeptide with at least 80% identity to amino acids 1-259 of SEQ ID NO:1, wherein said polypeptide binds Apo-2 ligand, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. '112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 21, 33, 47, 65, 79, 95, 111 and dependent claims 16-20, 48, 66, 67, 80, 81, 96 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite because it is unclear what the metes and bounds of "Apo-2DcR polypeptide" are. The specification says that his term includes variants (p. 12, first paragraph), and variants are about 80% identical to SEQ ID NO:1 and are agonistic or antagonistic modulators of apoptosis (p. 17, second paragraph). Because the activity is represented by two opposite functions, what structures are included are not clear. Note this claim is distinct from claims 105 and 112, which have a structural and functional limitation.

Claims 21 and 111 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: what process the host cell undergoes to effect production of the polypeptide.

Claims 33 and 47 are indefinite because it is unclear which polynucleotide comprises a heterologous polynucleotide sequence. Four different "polynucleotide sequences" are recited. Also, because each polynucleotide sequence already comprises a particularly recited sequence, and appears to be intended to comprise an additional sequence, said polynucleotide should "further comprise a heterologous polynucleotide sequence" if this is the intended meaning, instead of simply "comprise...."

Claims 65, 79 and 95 are unclear because each already comprises a first polynucleotide sequence with a particularly recited sequence, but appears to be intended to comprise an additional heterologous sequence. If this is the intention, it is suggested that said nucleic acid "further comprise a heterologous polynucleotide sequence".

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,261,801 (Wei et al., present in parent 08/878,168 and not included here) teaches "TRID" or "tumor necrosis factor receptor 5" ("TNFR-5") with the amino acid sequence of SEQ ID NO:2, which has the same sequence as the sequence of SEQ ID NO:1 of the instant application, and the encoding nucleic acid. Also taught (col. 1, lines 10-16) is the ability of TRID to bind TRAIL (also known as Apo-2 ligand, col. 3, lines 4-12). Vectors and host cells, including *E. coli*, yeast and CHO cells, comprising or expressing TRID or at least the extracellular domain thereof are taught in col. 14, line 27-36, and col. 33, line 30- col. 40. line

26. Chimeric proteins including those comprising an IgG sequence are taught in col. 21, lines 62- col. 22, line 10. For the reasons set forth in instant application's parent, this patent is not being applied as prior art due to assignment of effective filing date of August 7, 1997.

Allowable Subject Matter

Claims 32, 42, 44, 46, 60 and 75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 16-20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 105-110 and 112 are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

July 14, 2003

Claire M. Kaufman